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No. 03-779

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,
Petitioner,

v.

THE KROGER COMPANY, ET AL.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Motion for Leave to File *Amicus Curiae* Brief and Brief for *Amicus Curiae* the Center for the Advancement of Capitalism in Support of Petitioner

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Motion for Leave to File *Amicus Curiae* Brief

The Center for the Advancement of Capitalism (CAC), by its counsel and under Rule 37.2(b) of this Court's rules, respectfully requests leave to file the accompanying brief as *amicus curiae* in support of granting the petition for a writ of certiorari. Counsel for the petitioner, Andrx Pharmaceuticals, and counsel for Aventis Pharmaceuticals Inc. have consented to the filing of this brief. Andrx's counsel informed CAC that counsel for some of the respondents would not grant consent. None of the respondents have replied to CAC's requests for consent.

As set forth in the accompanying brief, CAC is a nonprofit organization that applies Ayn Rand's philosophy of Objectivism to contemporary public policy issues. CAC has particular expertise in the field of antitrust law, and our brief focuses on the potential impact of the decision below on the overall rights of businessmen in light of recent antitrust experiences.

CAC's brief succinctly addresses arguments not previously raised by Andrx. Accordingly, this brief will not

impose a substantial burden on the Court, and leave to file should be granted.

Respectfully Submitted,

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INTEREST OF AMICUS CURIAE[1]

The Center for the Advancement of Capitalism ("CAC") is a District of Columbia corporation organized in 1998, and exempt from income tax under § 501(c)(4) of the Internal Revenue Code. CAC's mission is to present analyses to policymakers, the judiciary, and the public to assist them in the identification and protection of the individual rights of the American people. CAC applies Ayn Rand's philosophy of Objectivism to contemporary public policy issues and provides empirical studies and theoretical commentaries on the impact of legal and regulatory institutions upon the rights of American citizens.

CAC's mission is to advance philosophical and legal principles that promote individual rights, limited

[1] No counsel for a party authored this brief in whole or in part, nor did any person or entity, other than CAC or its counsel, make a monetary contribution to the preparation or submission of this brief.

government, and capitalism. CAC has demanded the reexamination and ultimate abolition of the antitrust laws on practical, legal, and moral grounds—practically, because antitrust stifles production and harms consumers; legally, because antitrust abridges the rights of producers to trade what they make; and morally, because punishing successful production is unjust.

The instant case presents the question of whether the petitioner's patent infringement settlement results in a *per se* violation of the antitrust laws if the terms of the settlement do not provide the respondents with petitioner's generic alternatives to the patent-protected property. CAC believes that the decision below, if affirmed, will continue the erosion of property rights, including the right to enter and leave the market according to a businessman's self-interest and allow for even greater expansion of the evils of antitrust against businessmen. Because there are additional facts not addressed in the petitioner's petition that this Court should consider, CAC respectfully requests leave to file the accompanying brief containing discussion of this case.

SUMMARY OF ARGUMENT

The antitrust *per se* rule should not be expanded to include settlements, of any kind, between parties to a patent infringement settlement. This Court's previous decisions expanding the *per se* rule have had serious negative consequences on businessmen trying to live under the weight of conflicting antitrust mandates. For example, physicians subject to the *per se* rule have been effectively banned, under threat of antitrust prosecution, from negotiating contracts with managed care companies that reflect actual market prices. The result is a *de facto* price control on physician services. The same fate awaits pharmaceutical companies should the decision below in this case stand. Generic drug manufacturers in particular will be discouraged from entering the market since they face a

potential choice between risking costly patent infringement litigation on the one hand, and facing costly antitrust litigation on the other. This Court should not force companies to make such a fundamentally unfair and unreasonable choice.

ARGUMENT

The Sixth Circuit's decision should be reversed for the reasons stated by the petitioner, Andrx Pharmaceuticals. In addition, the Court should take this opportunity to reconsider the underlying antitrust principles that led to the Sixth Circuit's decision. This latest attempt to expand the *per se* rule neither clarifies the law nor advances antitrust's ostensible objective of protecting consumers. In its effort to create a judicial shortcut for class-action plaintiffs, the Sixth Circuit exposed key flaws in contemporary antitrust policy, and this Court should act to correct the errors before courts below inflict added damage.

Andrx and Aventis entered into two agreements that settled Aventis' Cardizem CD-related patent infringement claims. Under the first agreement, Aventis made quarterly payments to Andrx in exchange for Andrx's promise not to market generic Cardizem until the underlying patent litigation was concluded. The respondents in this case, all private purchasers of Cardizem, claim that this agreement violated their right to purchase Andrx's potential generic drug while the litigation was pending. Under the respondents' theory of "consumer rights," they were "denied" access to Andrx's generic drug between July, 1998, when Aventis' automatic 30-month stay under the Hatch-Waxman Act[2] expired, and June, 1999, when Andrx released Cartia XT, a Cardizem bioequivalent approved by the FDA and certified by Aventis as not infringing their patent. Moreover, in June of 1999, Aventis and Andrx signed a

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[2] 21 U.S.C. § 355.

second, final settlement disposing of all remaining patent infringement claims.

The respondents in this case (the plaintiffs below) claim that the first settlement was a *per se* antitrust violation because it amounted to a "naked, horizontal restraint of trade."[3] They argue that Andrx had a legal obligation to market generic Cardizem immediately upon receiving FDA approval, which was granted in August 1998, one month after the Hatch-Waxman stay expired. The respondents argue that consumer demand for a cheaper form of Cardizem overrode the threat that Andrx faced in marketing a product which infringed Aventis' patent. The Sixth Circuit essentially agreed with this premise, and held that Andrx committed a *per se* violation of the Sherman Act.

Under the government's current antitrust regime, businessmen are compelled to yield whenever the pursuit of their own interests may affect trade against the wishes of consumers. In this case, Andrx was confronted with a patent infringement suit. Rather then face months or years of resource-consuming litigation, Andrx reached an agreement with Aventis that satisfied both parties' interests. Subsequently, a number of third parties brought suit under the antitrust laws. The fundamental premise of their suit was that Andrx failed to sacrifice its interests to their needs.

In judging the respondents' antitrust claim, the Sixth Circuit applied a *per se* rule for one reason—misconceived judicial economy. If the enforcement of the Sherman Antitrust Act is ungainly, the responsibility rests with this Court for continuing to permit a statute that holds every transaction "in restraint of trade" to be illegal despite such a law's plain absurdity. Long antitrust trials are not the fault of businessmen who attempt to explain their conduct in terms of a larger understanding of the facts. They are the

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[3] Pet. App. 25a.

fault of a regimen that holds the rights of consumers above the rights of those who produce.

Yet, given the nature of antitrust, it is understandable why the labor-saving method of the *per se* rule appeals to the Court. Nevertheless, such interpretation presents the judiciary with a false alternative: violate the rights of businessmen quickly and easily versus a death by a thousand cuts. Neither interpretation is just. In keeping with the usual construction of antitrust law, this Court has reasoned that some antitrust violations are so obvious—even to "an observer with. . .a rudimentary understanding of economics"[4]—that consideration of the actual factual context of a case is unnecessary. According to this view, the courts may perform an extrapolation from their experience in dealing with certain classes of activities to declare that *all* instances of such activities are illegal *per se*. That is precisely what the Sixth Circuit did below—it dropped facts and context until all that remained was conveniently "conclusive proof" of Andrx's antitrust violation.

In turning back Andrx's request to consider the actual competitive effects of its agreement with Aventis, the Sixth Circuit clung to this Court's holding in *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982), which expanded the *per se* rule to include agreements among physicians to set fees jointly. The Sixth Circuit relied on a particular paragraph in *Marciopa*[5] which held that any attempt to question the *per se* rule's validity was, in essence, a waste of time and logic:

> The respondents' principal argument is that the per se rule is inapplicable because their agreements are alleged to have procompetitive justifications. The argument indicates a misunderstanding of the per se concept. The anticompetitive potential

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[4] *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

[5] *See* Pet. App. 20a.

> inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some. Those claims of enhanced competition are so unlikely to prove significant in any particular case that we adhere to the rule of law that is justified in its general application. Even when the respondents are given every benefit of the doubt, the limited record in this case is not inconsistent with the presumption that the respondents' agreements will not significantly enhance competition.[6]

The *Maricopa* doctrine emphasizes short term price competition as the objective of antitrust law. Accordingly, a defendant's claims of procompetitive benefits will generally fail when the government's objective is to ensure lower prices for the consumer in the short term. Andrx's procompetitive justifications failed in the courts below because nothing, according to antitrust doctrine, can ever justify a producer's intentional withholding of a product demanded by consumers, especially when that product is a low-cost alternative to an existing one.

Maricopa presents an ideal example of the *per se* rule in action. In that case, the Court dismissed the fact that the judiciary had "little antitrust experience in the healthcare industry"[7] and proceeded to strike down a common fee schedule arrangement that the dissent described as a "comparatively new method of providing insured medical services at predetermined maximum costs."[8] The Court ignored the new method, however, preferring rigid adherence to its *per se* doctrine:

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[6] *Maricopa*, 457 U.S. at 351.

[7] *Id.* at 349.

[8] *Id.* at 357 (Powell, J., dissenting).

> [T]he argument that the per se rule must be rejustified for every industry that has not been subject to significant antitrust litigation ignores the rationale for per se rules, which in part is to avoid "the necessity for an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable - an inquiry so often wholly fruitless when undertaken."[9]

But there were consequences to the Court's decision not to undertake a "wholly fruitless" inquiry. When *Maricopa* was decided, physicians were not competing in a free market. By 1982, Congress had enacted legislation to cut federal expenditures for Medicare and Medicaid through what amounted to a governmental price-fixing scheme. Rather than permit the market to determine prices for physicians' services, Medicare and Medicaid set all prices on a take-it-or-leave-it basis. Following that lead, private managed care insurers (themselves the product of government intervention) adopted similar reimbursement schemes. CAC holds that these regulations were inherently unjust because Congress was consumed with cutting patients' costs at the expense of physicians.

Acting under *Maricopa*, the Federal Trade Commission and Department of Justice have used antitrust law to prevent physicians from acting in their rightful interest. Under current policy, "competing" physicians may not jointly negotiate contracts with managed care companies and other third-party payers. This is *per se* price fixing under *Maricopa*. The exception to this rule arises when physicians engage in financial "risk sharing," as defined by the

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[9] *Id.* at 351 (quoting *Northern Pacific R. Co. v. U.S.*, 356 U.S. 1, 5 (1958).

government. Currently, the FTC and DOJ allow two forms of risk sharing.[10] Neither model has proved to be financially viable for physicians; yet any deviation from these models subjects physicians to *per se* antitrust prosecution.[11]

Since 2001, the FTC and DOJ have brought civil charges against more than 11,000 physicians for illegal price fixing.[12] Most of the physicians denied wrongdoing, but settled to avoid the cost of civil litigation, not to mention potential criminal charges, since any *per se* antitrust violation can trigger the antitrust laws' criminal penalties.[13] In all of these cases, the government declared that physicians must negotiate with payers on their own, and not as a group. The government's position ignores both economic reality and the rights of physicians to the fruits of their own work. Individual physicians cannot negotiate meaningfully with multibillion-dollar insurance companies. Moreover, if enough physicians individually reject a proposed contract, the FTC and DOJ could infer a price-fixing conspiracy and bring charges. It follows that, under antitrust, the only genuine refuge for physicians is the acceptance of third-party contract offers without negotiation.

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[10] *See* U.S. Dep't of Justice and Federal Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care* (August 1996) (available at http://www.ftc.gov/reports/hlth3s.htm).

[11] For additional discussion of the FTC-DOJ policy and its impact, *see* Center for the Advancement of Capitalism, *Comments on the Proposed Consent Order in the Matter of Obstetrics & Gynecology Corp. of Napa Valley, et al.* (May 1, 2002) (available at http://www.capitalismcenter.org/Campaigns); Citizens for Voluntary Trade, *Comments on the Proposed Final Judgment in United States v. Mountain Health Care, P.A.*, 68 Fed. Reg. 44,577-44,591 (July 29, 2003).

[12] Citizens for Voluntary Trade, *Physician Groups Prosecuted by the FTC and DOJ Since 2001* (revised December 11, 2003) (available at http://www.voluntarytrade.org/physician_table.pdf).

[13] *See* Dep't of Justice, *United States Attorneys' Manual*, Title 7 ("virtually all antitrust offenses likely to be prosecuted by a United States Attorney's office will be governed by the per se rule") (available at http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title7/ant00007.htm).

The post-*Maricopa* physicians' market is a triumph of range-of-the-moment antitrust policy. Physicians are afraid to set their prices, and the *per se* rule allows regulators and the courts to remain ignorant of other factors affecting the market. But while the present system maintains the prosperity of managed care companies and the antitrust bar, the *Maricopa* doctrine has done nothing for the consumers of healthcare. No evidence demonstrates that insurance costs for individual customers are lowered by subjecting physicians to the *per se* rule. Indeed, physicians' costs have remained steady or declined in many markets, yet premiums have increased steadily and substantially. Had the *Maricopa* court not excused antitrust regulators from considering the competitive context of the entire market, policymakers might have reached a differing conclusion about the actions of physicians. By foreclosing all discussion of the issue in 1982, this Court effectively invited the FTC and DOJ to confer upon physicians the status of scapegoats for the continuing public policy problem of rising healthcare costs.

Andrx and the pharmaceutical industry are now at the crossroads faced by physicians in *Maricopa*. Drug manufacturers have become the most recent targets of legislative and executive displeasure over rising healthcare costs. Despite the unprecedented success of pharmaceutical companies in producing effective medicines, critics continue to focus on the antitrust theme of short-term price competition. As with physicians, *price fixation* excludes all other factors from the discussion. While total U.S. pharmaceutical outlays rose by more than 17% from 2000 to 2001, according to the NIHCM Foundation[14], these increases are not the product of price-fixing conspiracies hatched by pharmaceutical companies. Indeed, NIHCM found that only 37% of the 2001 cost rise was due to manufacturers' price

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[14] NIHCM Research & Education Foundation, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* at 4 (revised May 6, 2002) (available at http://www.nihcm.org/spending2001.pdf).

increases. The remaining 63% was attributed to the increased use of drugs and the shift to newer, more expensive medicines[15]: "Simply put, Americans are demanding, and physicians are prescribing, a higher volume of medicines each year."[16]

In addition, consumer demand is driven upward by government intervention in healthcare. The federal government accounts for over 45% of overall health spending in the U.S., and tax subsidies for private insurance health premiums account for another 10%.[17] When the government's drug costs increase, the pressure on the federal budget has led legislators and the White House to seek governmental solutions. For example, Congress recently passed statutes designed to incorporate prescription-drug benefits into Medicare.[18] Such statutes increase total government spending on drugs. CAC holds that when this spending inevitably reaches unsound and unsustainable levels, Congress will respond by shifting the responsibility to the pharmaceutical manufacturers in the form of price controls rather than by repealing its flawed benefit package.

Pharmaceutical companies are pressured to lower prices at the same time that they face increased regulatory burdens on their production. The development of new drugs is particularly costly. One study estimated that it takes 10 to 15 years and $802 million to bring a new drug through the system from conception, to research, to FDA approval.[19]

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[15] *Id.* at 6.

[16] NIHCM Research & Education Foundation, *Prescription Drug Expenditures in 2000: The Upward Trend Continues* at 9 (May 2001) (available at http://www.nihcm.org/spending2000.pdf).

[17] Doug Bandow, *Demonizing Drugmakers: The Political Assault on the Pharmaceutical Industry*, Cato Institute Policy Analysis No. 475 at 3 (May 8, 2003) (available at http://www.cato.org/pubs/pas/pa-475es.html).

[18] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 (December 8, 2003).

[19] Bandow, *Demonizing Drugmakers* at 9.

Most of these costs are borne by the manufacturer and not by the government. Yet, when a new drug is patented, there is a near-instantaneous demand to bring a cheaper generic drug to market as quickly as possible. This is what led Andrx to develop a bioequivalent to Cardizem in the first place.

But Andrx cannot serve several masters simultaneously. It cannot seek to maximize profits and increase shareholder value while accommodating conflicting demands from government regulators and class-action attorneys who demand early access to a generic drug. In this case, Andrx's 1995 decision to produce generic Cardizem has cost it more than eight years of litigation: Aventis' patent infringement suit, followed by the FTC's 2001 antitrust investigation, and finally the class-action lawsuits that led to the petition now before this Court. If anything, this legal burden alone serves as a far greater restraint on competition than could any agreement between Andrx and Aventis.

Should this Court deny the petition or affirm the Sixth Circuit, it will send a message to generic drug manufacturers that their efforts may be better spent not competing. By subjecting some or all patent settlements to the *per se* rule, Andrx and its sister companies will face an unenviable choice in the future: Risk losing a patent infringement lawsuit, or settle and risk costly antitrust prosecution at the hands of numerous state attorneys general and a well-financed plaintiff's bar. Given this choice, many generic drug companies may exercise a third option taken by many physicians in the post-*Maricopa* era: They'll leave the market entirely.

The essence of the *per se* rule is the "but for..." mentality: "But for" Andrx and Aventis' agreement, the respondents argue, they would have had a cheaper drug sooner. Yet the one-year delay created by the Andrx-Aventis agreement is insignificant when compared with the government-imposed restraints on the pharmaceutical industry and the healthcare

market in general. This is why a *per se* rule cannot be applied reasonably. Without a fuller understanding of the true operative context of the marketplace, the courts will be reduced to making blind guesses as to what *might* happen in a given market under a limited set of objectively unwarranted assumptions. This fails to benefit consumers and violates the rights of producers. The mistakes of *Maricopa* are instructive. The Court has it within its power to set things right.

This case ultimately comes down to a question of property rights. Initially, Aventis sued Andrx over patent infringement. That issue was settled in accordance with established common and statutory law. By contrast, the respondents' case obliterates patent rights in the name of so-called "consumer rights" and obliterates Andrx's right to enter and leave the market for its own sake. If the Sixth Circuit's decision is allowed to trump the patent settlement, it will send an unmistakable message that this Court does not value property rights. CAC believes that such a message finds no support in the Constitution. The conflict between the Sixth and Eleventh circuits ought be resolved in favor of the latter and the Court should put the principle of property rights ahead of a judicial expansion of the *per se* rule.

CONCLUSION

For the reasons discussed above, and the reasons given by Andrx in its petition, the writ of certiorari should be granted.

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